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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,445	09/16/2004	Joseph P Orban III	2786	6710
Covidien 60 Middletown Avenue North Haven, CT 06473			EXAMINER SMITH, FANGEMONIQUE A	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 07/24/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/508,445

Applicant(s)

ORBAN, JOSEPH P

Examiner

Fangemonique Smith

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on April 1, 2009. Examiner acknowledges the amendment of claims 1, 19, 28, 31 and 33. Claims 1-35 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7-9, 12-16 and 18-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (U.S. Patent Number 5,215,521) in view of Bardes et al. (U.S. Patent Number 5,149,159).

In regard to claims 1-5, 7-9, 12-16 and 18-35, Cochran discloses a tissue removal device and method comprising an elongate shaft (26) having a distal end and a proximal end, wherein the elongate shaft defines a longitudinal axis. Cochran et al. further disclose a bag support (26) defining an opening, the bag support being collapsible and expandable to open and close the opening. The device includes a conical shaped bag (22) operatively connected to the bag support. The bag (22) has an open first end operatively secured to the bag support and a closed end. When in a collapsed position, the bag support (26) of the Cochran et al. device substantially closes the first end of the bag. Cochran et al. disclose a tube (16) for receiving the shaft, bag support and bag. The Cochran et al. device has folds approximately parallel with the

longitudinal axis as shown in Figure 3. The bag assembly includes a sheath (20) disposed about the bag assembly and the sheath is formed of a plastic lattice construction, which is inherently capable of having a weakness for breaking away from the bag (col. 9, lines 40-50). Cochran et al. additionally disclose an actuation system operatively connected to the sheath in order to facilitate removal of the sheath from the bag assembly (col. 10, lines 28-35). The actuation system includes a tear line formed in the sheath to facilitate tearing of the sheath (col. 10, lines 1-5 and 28-35). Also included with the actuation member is an expandable member (24, 26) positioned within the bag assembly. The expandable member is initiated remotely from the bag. Cochran et al. disclose a tissue removal device wherein the bag (22) is conical in shape and has a proximal edge and a distal edge. The bag includes a slot formed in the vicinity of the bag support near the proximal edge to enable the diameter of the bag to be adjusted. The device disclosed by Cochran et al. further includes a control line (26). Upon use, the Cochran et al. device includes method steps of folding the bag such that the proximal edge is capable of crossing the distal edge (Fig.3) and the folds are approximately parallel to the longitudinal axis. Use of the Cochran et al. device further includes method steps of closing the upper end of the bag using the support, transforming the bag from an open to a closed position. The bag is folded onto itself and the folded bag is placed into a sheath. Cochran et al. disclose the features of the Applicant's invention as described above. Although the Cochran et al. device is capable of folding transversely, Cochran et al. do not specifically disclose this feature. Bardes et al. disclose a sample retrieval instrument having a bag with at least one transverse fold at its distal end. The transverse fold is located such that the cross sectional area of the distal end of the apparatus is reduced when the fold is present forming a pouch area which allows a specimen to

be collected. The pouch includes a first and second edge with bag folds including at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figure 7). Devoid the fold, the area would have a larger cross section.

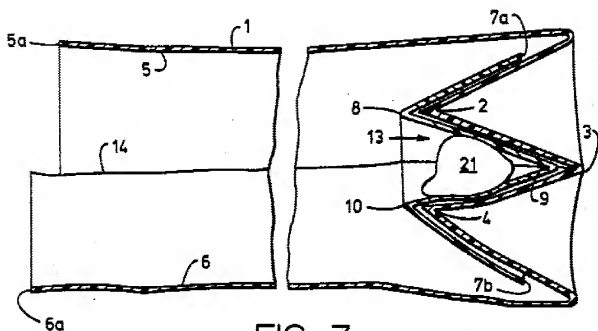
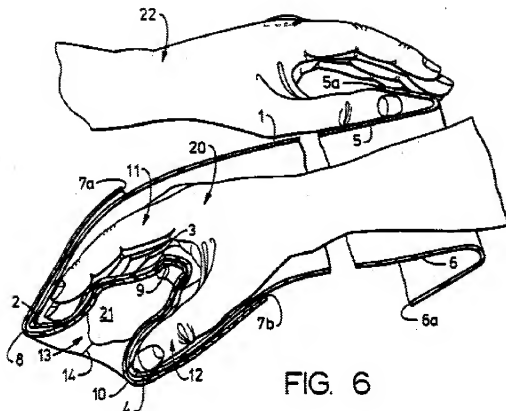


FIG. 7

The fold of the bag increases durability of the bag as taught by Bardes et al. Bardes et al. further teach folding the bag onto itself to allow the proximal terminal edge to be aligned with the longitudinal axis. This folding method is shown in Figure 6 of the Bardes et al. reference.



It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue removal device and method, similar to that disclosed by Cochran et al., to include a bag which folds transversely, similar to that disclosed by Bardes et al., to find another way to collapse the bag while maintaining the sample within the bag.

4. Claims 1, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (U.S. Patent Number 5,215,521) in view of Bardes et al. (U.S. Patent Number 5,149,159) and in further view of Summer (U.S. Patent Number 5,899,694).

In regard to claims 1, 4 and 6, the combined references of Cochran et al. and Bardes et al. disclose a tissue removal device and method, the combination fails to specifically disclose the sheath being fabricated from a flexible heat-shrinking polymer. Summer discloses a sheath

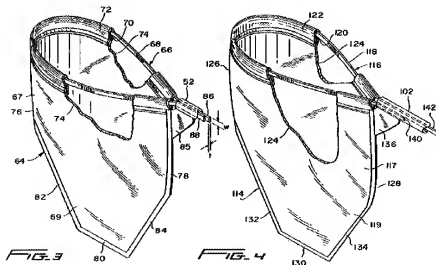
fabricated from a flexible heat-shrinking polymer. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue removal device and method, similar to that disclosed by the combined references of Cochran et al. and Bardes et al., to include a sheath made from a heat-shrinking polymer, similar to that disclosed by Summer, to allow the sleeve to assume other shapes including a bent shape if desired.

5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (U.S. Patent Number 5,215,521) in view of Bardes et al. (U.S. Patent Number 5,149,159) and in view of Snow et al. (U.S. Patent Number 6,402,722).

In regard to claims 10 and 11, the combined references of Cochran et al. and Bardes et al. disclose the features of the Applicant's invention as described above. The combined references do not disclose including a cord operatively connected to the tear line for facilitating the tearing of the sheath. Snow et al. disclose a cord (18) operatively connected to a tear line for facilitating the tearing of a sheath along the tear line. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue removal device and method, similar to that disclosed by the combined references of Cochran et al. and Bardes et al., to include a cord operatively connected to the tear line, similar to that disclosed by Snow et al., to have better control over when the sheath is separated from the rest of the device.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cochran et al. (U.S. Patent Number 5,215,521) in view of Bardes et al. (U.S. Patent Number 5,149,159) and in further view of Kammerer et al. (U.S. Patent Number 5,480,404).

In regard to claim 17, the combined references of Cochran et al. and Bardes et al. disclose a tissue removal device and method. The combination discloses a tissue removal device wherein the bag is conical in shape and has a proximal edge and a distal edge. The bag includes a slot formed in the vicinity of the bag support near the proximal edge to enable the diameter of the bag to be adjusted. Although the combined references disclose the features of the Applicant's invention as described above, the combination does not disclose having a bag with a trapezoidal shape. Kammerer et al. disclose a surgical tissue retrieval instrument having a bag having at least one transverse fold. The device disclosed by Kammerer et al. includes a pouch having a trapezoidal shape for the collection and removal of tissue samples. The pouch includes a first and second edge with bag folds including at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figures 3 and 4).



It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue sampling device, similar to that disclosed by the

combined references of Cochran et al. and Bardes et al., to include a bag with a trapezoidal shape, similar to that disclosed by Kammerer et al., to provide a larger collection area for the sample being collected.

Related References

7. There were additional references that were found during searching Examiner feels are relevant to the invention disclosed by the Applicant.

a. Dean (U.S. Patent Number 6,745,894) discloses a waste removal device for collecting waste material. The Dean reference discloses having a transverse fold that reduces the transverse area upon folding.

b. Brigham (U.S. Patent Application Publication Number 2003/0236507) includes a containerless tissue sample collection trap which has a flexible filter with a flat shape. Upon folding the flexible filter transversely, the axial length increases and the transverse area is reduced.

These references were not used as a basis of the rejection above. However, Examiner feels the references include related subject matter of the claimed invention.

Response to Arguments

8. Applicant argues the Examiner failed to disclose the specific structure in Bardes that is relied upon for disclosure of the at least one transverse fold. Examiner submits, the previous office action dated January 9, 2009 disclosed the Bardes et al. reference as having a transverse fold and directed Applicant's attention to Figure 7 of the Bardes et al. reference for clarification

of the fold being relied upon as disclosing the transverse fold. Examiner respectfully disagrees with Applicant's statement that the previous office action was insufficient regarding informing Applicant of how Bardes et al. includes features of Applicant's invention. Examiner has referred to the same figure in arguments above and included an additional figure with a detailed explanation for additional clarification.

9. Applicant argues the combined prior art references fail to disclose at least one transverse fold such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension. Examiner respectfully disagrees. Upon folding the bag assembly to form the gusset shape at the distal end of the device, the transverse area at the base of the device is reduced. Examiner submits as stated above, if the folds were not present, the cross sectional area at the end of the device would be larger.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736